

EXHIBIT H

Original Article: Clinical Investigation

Tension-free vaginal tape procedure without preoperative urodynamic examination: Long-term outcome

Pia Heinonen,¹ Seija Ala-Nissilä,² Pentti Kiilholma¹ and Eija Laurikainen²¹Turku University, and ²Department of Obstetrics and Gynecology, Turku University Hospital, Turku, Finland**Abbreviations & Acronyms**

BMI = body mass index

DIS = Detrusor Instability Score

EQ-5D VAS = European quality of life – visual analog scale

EuroQoL-5D = European quality of life-five dimensions

IIQ-7 = Incontinence

Impact Questionnaire-7

ISD = intrinsic sphincteric deficiency

MUI = mixed urinary incontinence

NS = not significant

SD = standard deviation

SUI = stress urinary incontinence

TOT = transobturator tape

TVT = tension-free vaginal tape

UDI-6 = Urogenital

Distress Inventory-6

UISS = Urinary Incontinence Severity Score

UUI = urgency urinary incontinence

VAS = visual analog scale

Objectives: To evaluate the long-term outcome of the tension-free vaginal tape procedure.**Methods:** A total of 191 patients were operated on with tension-free vaginal tape between January 1998 and May 2000. Of these, 127 (66%) had stress urinary incontinence, 64 (34%) had mixed urinary incontinence and 39 (20%) had recurrent incontinence. A total of 34 (18%) patients had had concomitant surgery. The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. Tension-free vaginal tape was carried out under local (82%) or spinal (18%) anesthesia. After a mean of 10.5 years follow up, the assessment included a gynecological examination and a supine stress test. Subjective outcome was evaluated with Urinary Incontinence Severity Score, Detrusor Instability Score, visual analog scale, European quality of life-five dimensions, European quality of life – visual analog scale and short versions of Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6. Objective cure was defined as a negative stress test and an absence of reoperation for incontinence during the follow up.**Results:** A total of 138 (72%) of 191 patients were evaluated. Patients with minimally invasive surgery before operation had significantly higher scores in Urinary Incontinence Severity Score, Detrusor Instability Score, Incontinence Impact Questionnaire-7 and Urogenital Distress Inventory-6 at follow up than the patients with stress urinary incontinence ($P < 0.01$). Recurrent incontinence and concomitant surgery did not affect the long-term outcome. Three patients (2.3%) had late-onset adverse events. The objective and subjective cure rates were 90% and 78%, respectively.**Conclusions:** The tension-free vaginal tape procedure is effective and safe even after 10 years. The objective cure rate is high, but the subjective outcome is significantly lower in mixed urinary incontinence patients compared with patients with pure stress urinary incontinence. Recurrent stress urinary incontinence does not affect the outcome, and tape-related problems are rare.**Key words:** follow-up studies, minimally invasive surgery, stress urinary incontinence, suburethral slings, tension-free vaginal tape.**Correspondence:** Pia HeinonenM.D., Department of Obstetrics and Gynecology, University of Turku, Turku 20520, Finland.
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accepted 26 May 2012.

Online publication 24 June 2012

Introduction

The overall prevalence of female SUI among females over the age of 18 years is approximately 30%,¹ but is increasing with age.² SUI can be treated surgically, and minimally invasive techniques have been developed to minimize surgical complications, and to improve outcome and patient satisfaction. The TVT technique was introduced by Ulmsten in 1996, and has become the gold standard for treating female SUI.³ In TVT, a tape is placed loosely under the midurethra through the retropubic space. According to the few long-term follow-up studies that are available, cure rates have been satisfying for TVT and mesh-related adverse events are rare.^{4,5}

The aim of the present study was to report the effectiveness, subjective and objective outcomes, and late adverse events among patients who underwent TVT a mean of 10.5 years

ago without preoperative urodynamic examination. The short-term outcome of the present study population has already been published.⁶

Methods

The present study is a follow-up study of 191 patients operated on with the TTV procedure between January 1998 and May 2000 at the Department of Obstetrics and Gynecology in the Turku City Hospital, Turku, Finland. The Departments of Obstetrics and Gynecology of the Turku City Hospital and of the University Hospital were joined in 2004, and therefore this follow up was not carried out in the same hospital as the original operation. All the operations were carried out by senior gynecologists. Most (90%) of the procedures were carried out by one surgeon (PK). The study population has been presented previously.⁶ A total of 127 patients (66%) had SUI and 64 (34%) had MUI with SUI symptoms dominating. In the original cohort, 39 (20%) patients had recurrent incontinence with previous anti-incontinence operations, which were colposuspension in 23 cases (19 open and 4 laparoscopic), vaginal incontinence operation in 12 (including one TTV) and periurethral injection in six patients. Furthermore, one patient had undergone bladder neck dissection because of retention and overflow incontinence.

The diagnosis of incontinence was based on a history of leakage during stress and physical examination with a supine stress test in all patients. In over half of the cases the UISS⁷ (Appendix 1), the DIS^{7,8} (Appendix 2) was also filled in. Urogynecological perineal ultrasonography was carried out to examine the patients who had a history of MUI in order to verify the SUI component.⁹ Also, of the 39 patients with recurrent incontinence, 22 patients underwent preoperative ultrasonography. In the original study population, all patients were primarily treated with pelvic floor exercise including instructions for bladder training and secondarily with anti-cholinergic medication if required.⁶

Vaginal, systemic or combined hormone replacement therapy was used by 119 (62%) patients. The procedure was carried out as previously described³ under local (82%) or spinal (18%) anesthesia with perioperative cystoscopy. The tape (TTV Gynecare; Ethicon, Somerville, NJ, USA) was loosely placed under the midurethra. An intraoperative stress test with 300 mL bladder filling was used to adjust the tape in all patients regardless of the method of anesthesia. One dose of 500 mg metronidazole was given intravenously for antibiotic prophylaxis immediately before the operation. Concomitant surgery was carried out in 34 (18%) patients; 13 procedures were carried out for pelvic organ prolapse and 21 vaginal hysterectomies were carried out because of heavy bleeding or uterine fibroids.

After a mean of 10.5 years (range 9–12 years), postal questionnaires were sent to all patients together with an

invitation for a charge-free follow-up visit at the Turku University Hospital, Outpatient Clinic of Gynecology. A reminder was sent to those who did not respond to the first questionnaire. Attempts were made to contact non-respondents by telephone. They were asked about symptoms of SUI, urgency or UUI and any late adverse events, as well as satisfaction with the operation.

Subjective outcome was evaluated with condition-specific questionnaires: the UISS, the DIS, short versions of the IIQ-7 and the UDI-6, and a VAS 0–100.¹⁰ UISS and DIS have been designed by the urogynecological working groups of Finnish and Nordic Gynecological Societies. UISS demonstrates symptom severity and the impact of urinary incontinence on everyday life, and DIS symptoms of detrusor instability and its degree. These questionnaires are widely used in Finland, as in other Scandinavian countries.^{7,8} In the DIS questionnaire, scores ≤7 refer to pure SUI and the more scores that are calculated, the more symptoms of urgency exists.⁸ The patients' general quality of life and health was assessed with EQ-5D and EQ-5D VAS. If a patient left more than two items unanswered in the IIQ-7 or UDI-6 questionnaires, a total score was not calculated. The patient was considered to be satisfied with the procedure if the total score of the IIQ-7 questionnaire was 0–7¹¹ and if they expressed satisfaction at the telephone interview. If the score in the DIS questionnaire was more than 7, and if the patient had moderate or severe frequency or urgency (scores 2 or 3) in questions one and two of the UDI-6 questionnaire, the patient was considered to have urgency or UUI.

At the follow-up visit, a gynecological examination and a supine stress test with a 250–300 mL bladder volume were carried out. The hospital records of all the patients were reviewed to examine whether the patients had had visits to the hospitals in the Hospital District of Southwest Finland. This was done to acquire information on later acquired systemic diseases, gynecological or anti-incontinence operations, urinary symptoms and adverse events after the TTV-operation.

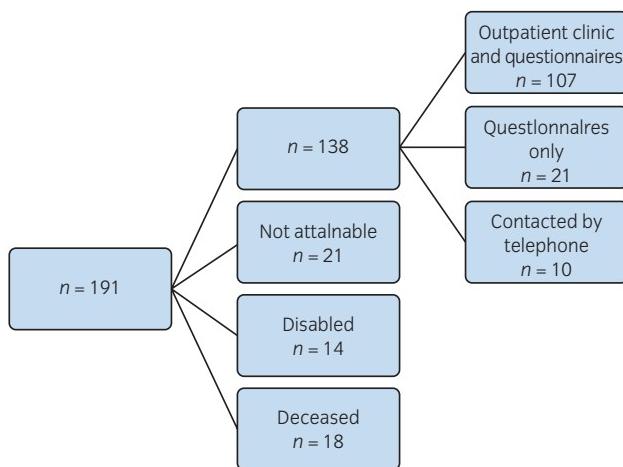
Objective cure was defined as a negative stress test and no need for a reoperation for SUI.

The SAS system for Windows version 9.2 (SAS Institute, Cary, NC, USA) was used for tabulations and statistical analysis.

The study was approved by the Ethics Committee of the Hospital District of Southwest Finland.

Results

A total of 138 (72%) out of 191 patients were evaluated at a mean of 10.5 years postoperatively (Fig. 1). Of these, 127 (66% of the original cohort) both answered the questionnaires and visited the outpatient clinic. A total of 21 (11%) patients were unwilling to attend the follow-up visit and only returned the questionnaires. A total of 18 (9% of the

**Fig. 1** Study population.

original cohort) patients had died during the follow up of unrelated causes. Of the 35 (21%) patients who did not participate in the evaluation, 21 (11%) were not reached and 14 (7%) were too disabled to attend, mainly because of cognitive disorders. Ten patients could be contacted by telephone.

The mean follow-up time was 126.5 months (range 108–145 months). The mean age at the follow up was 69 years (range 48–93 years). The patient characteristics are presented in Table 1.

Out of 64 patients with MUI preoperatively, 58% (37 patients) and 80% (101 patients out of 127) of SUI patients participated in the present study. By the time of the surgery, the mean age for MUI patients who didn't participate in the present follow-up study was 67 years, whereas the mean age for the whole study group was 60 years.

Of the 128 patients, 100 (78%) had a score of 0–7 in IIQ-7, which is considered as a satisfactory subjective outcome.¹¹ The results of the questionnaires are presented in Table 2. In all condition-specific questionnaires (UISS, DIS, UDI-6, IIQ-7), all the results were significantly poorer in patients with MUI compared with those with SUI (Table 2). Also, in questionnaires assessing patients' general quality of life and health (EQ-5D and EQ-5D VAS), MUI patients had significantly poorer results. Five patients did not reply to more than two questions in the IIQ-7 or UDI-6 questionnaires, and therefore a total score was not calculated for these patients. Ten out of 37 MUI patients (27%) had persistent urgency at the time of follow up. Six (6.6%) patients developed de novo urgency. The occurrence of urgency was of similar frequency among patients aged over 7 years as among younger patients (34% vs 47%, $P = 0.18$).¹²

A total of 18 (14%) patients had a DIS score >7, and at the same time moderate or severe scores at the first and the second questions of the UDI-6 questionnaire indicating urgency or UUI. Patients with chronic illnesses had a poorer health-related quality of life, as assessed with EQ-5D VAS

Table 1 Characteristics of the patients in the original cohort operated on using TTV and in patients evaluated objectively or with the questionnaires after a mean of 10.5 years postoperatively

	Original cohort (n = 191)	Evaluated cohort (n = 128)†
Median age (years)	60	68
Median BMI	27	26
Estrogen (n)‡	119	77
Chronic illnesses (n)§	74 (39%)	100 (78%)
• Diabetes	3	10
• Cardiovascular	61	68
• Neurological	4	7
• Respiratory	14	9
Previous gynecological surgery (n)	110	
• Incontinence surgery	39	
• Hysterectomy	77	
• Vaginal prolapse surgery	24	
Surgery after the TTV operation (n)		
• Incontinence surgery	6	
• Bulking agent¶	1	
• Hysterectomy	5	
• Vaginal prolapse surgery	4	

†The 10 patients contacted by telephone are not included in this cohort. ‡Vaginal and/or systemic estrogen. §One patient might have had one or more chronic illnesses. ¶Polyacrylamide hydrogel.

and EQ-5D than healthy patients (65 vs 74 and 8.1 vs 9.3, respectively, $P < 0.05$ for both). In regard to the patients with recurrent SUI, 12 (31%) out of 39 patients were diagnosed to have MUI preoperatively. There were no statistically significant differences in the results of the questionnaires compared with patients with primary SUI and those with recurrent SUI (Table 3). Of the 10 patients who were contacted by telephone, seven were continent and satisfied with the operation, whereas two of the patients had MUI and one UUI.

Among the 107 patients who were eligible for objective evaluation, a stress test was negative for 100 (93%) patients. The TTV procedure was considered a failure in 11 (10%) patients: six patients had undergone a repeat anti-incontinence procedure and a stress test was positive in six patients, including one reoperated patient with a positive stress test. Repeat anti-incontinence procedures were TTV in one patient and TOT in five patients. One patient of the latter group has had two transobturator procedures; with outside-in and inside-out technique. All these patients are now stress continent, though two of them are using anticholinergic medication for urgency symptoms. These reoperated patients were not included in the analysis. The mean

Table 2 Results of the questionnaires at the time of follow up a mean of 10.5 years after the TVT operation

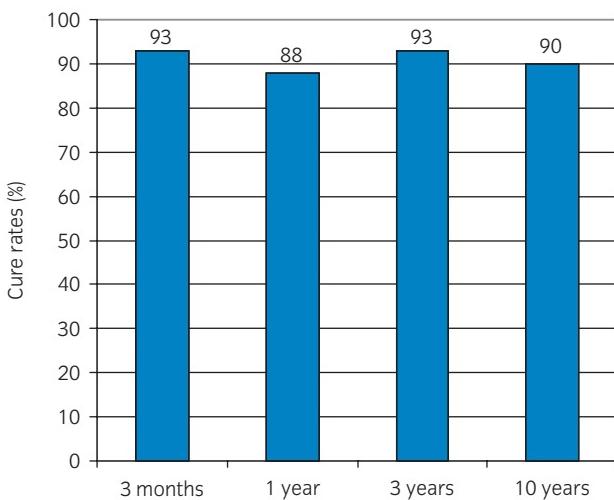
<i>n</i> = 128	SUI† mean ± SD	Range	MUI† mean ± SD	Range	P-value‡
IIQ-7 (0–21)	1.8 ± 3.5	0–21	5.7 ± 5.9	0–21	<0.001
UDI-6 (0–18)	3.6 ± 2.9	0–13	7.1 ± 4.9	0–17	<0.001
EQ-5D VAS (0–100)	73 ± 21	10–100	63 ± 19.5	15–100	<0.05
EQ-5D (6–18)	8.3 ± 1.8	6–14	9.1 ± 2.1	6–16	<0.05
VAS (0–100)	22 ± 25.4	0–90	42.7 ± 34	0–100	<0.001
UISS (0–100)	12.9 ± 16.6	0–78	33 ± 25.4	0–90	<0.001
DIS (0–20)	5.3 ± 3.1	0–11	8.9 ± 4.2	0–16	<0.001

†SUI or MUI before the TVT operation. ‡P-value representing differences in scores in SUI and MUI patients.

Table 3 Results of the questionnaires evaluating subjective outcome in patients with primary and recurrent SUI after the 10.5 years follow-up

	Primary SUI mean ± SD	Range	Recurrent SUI mean ± SD	Range	P-value
IIQ-7 (0–21)	9.9 ± 5	0–28	9.3 ± 3.5	7–20	NS
UDI-6 (0–18)	10.6 ± 4.2	0–23	9.8 ± 3.2	6–19	NS
EQ-5D VAS (0–100)	71.4 ± 19.6	10–100	65.2 ± 65.2	15–100	NS
EQ-5D (6–18)	8.4 ± 1.9	6–16	9.2 ± 2.0	7–14	NS
VAS (0–100)	27.6 ± 29.5	0–95	28.4 ± 28.4	0–100	NS
UISS (0–100)	19.7 ± 22.2	0–90	16.3 ± 19.5	0–70	NS
DIS (0–20)	6.3 ± 3.9	0–16	6.8 ± 3.4	0–13	NS

NS indicates P-value >0.05.

**Fig. 2** Objective cure rates after the TVT operation at 3 months, 1 year, 3 years and 10 years follow up. Objective cure rates after 3 months, 1 year and 3 years. Reproduced from Laurikainen et al.,⁶ with permission. ■, %.

age of the six patients with a positive stress test was 79 years. Two of these patients were primarily operated on because of recurrent SUI. The objective cure rate for the patients with MUI before TVT was 93% (37/40 patients)

and with SUI it was 94% (63/67). The overall objective cure rate was 90% of the 107 evaluated patients. The results and cure rates at earlier time-points have been presented in a previous publication (Fig. 2).⁶

In this evaluated cohort, local anesthesia was used in 88% of the patients and spinal anesthesia in 12%. The type of anesthesia did not affect the outcome, nor did any concomitant surgical procedures affect the scores.

The TVT tape was cut below the urethra in two patients; one because of urinary retention at 1 year after the operation and another because of pain at 8 years. The symptoms of both patients disappeared after the re-intervention and the patients remained stress continent. The patient with urinary retention also had urgency incontinence, which was successfully treated with anticholinergic medication and pelvic floor physiotherapy. Recurrent urinary tract infections and pain during urination appeared in one patient 9 years after the TVT procedure. A fibercystoscopy was carried out by a urologist and a small part of calcified tape was found to be eroded into the bladder on the right side of the bladder neck. A visible part of the tape was resected at repeat cystoscopies three times. At the latest control more than 11 years after the operation, the patient still had recurrent urinary tract infections and difficulties in emptying the bladder. An abdominal computed tomography and cystos-

copy was scheduled to locate the exact position of the tape. The original TTV operation was carried out uneventfully. A cystoscopy was carried out twice after the insertion of the tape at both sides routinely, as advised in the original TTV technique during the primary operation,³ and no abnormal findings; for example, perforation or folding of the bladder wall, were discovered. Hospital records of the original cohort did not show any additional complications.

Discussion

The TTV-procedure has become the gold standard of female incontinence surgery. Short-term efficacy and safety have been well demonstrated in numerous studies,^{13,14} but there is a paucity of long-term data. In two studies with follow up more than 10 years, objective cure rates were 90% and 84%, respectively.^{4,5} Accordingly, in the present study, objective cure of SUI was found to be 90% and subjective cure 78%. The TTV operation is a highly standardized procedure with a routine performance including an intraoperative stress test under local anesthesia, and a cystoscopy after insertion of the tape at each side.³ When TTV was introduced in Finland, systematic, nationwide, hands-on training for gynecological surgeons was executed.¹⁵ This might contribute to the relatively high cure rates after the long-term follow up.

In the present follow-up study, the outcome could be evaluated objectively in 107 patients and subjectively in 138 patients of the 191 patients who had undergone the TTV procedure a mean of 10.5 years ago. A total of 18 patients had died, and 14 were unable to attend a charge-free follow-up visit to an outpatient clinic. Some patients could not be reached by postal invitation, and some declined participation, partially as they were initially operated on in a hospital different from the follow-up site. The readiness to participate the present study might also have been affected by the relatively high median age of the patients, 68 years. The oldest participant was 93 years. However, the risk of non-responder bias has to be taken into account when interpreting the results of the present study.

There are some studies showing that TTV is also an effective way to treat patients with MUI.^{13,16} In contrast, in the present study population,⁶ the short-term cure rate of the patients with MUI was significantly lower than of the SUI patients at 36 months of follow up, 69% versus 97%. The same tendency also persisted in the long-term follow up. However, just 58% of the MUI patients participated the present study. The mean age of MUI patients was 7 years higher than that of the SUI patients, which might have affected the readiness of MUI patients to attend. Subjective outcome is likely to be poorer with MUI patients, because of persistent urgency or UUI symptoms. It is obvious, that the stress test is not ideal for testing urgency incontinence symptoms objectively. Omitting preoperative urodynamic testing might be associated with poorer subjective results in

MUI patients. The risk of an unsatisfying result is higher with a patient with MUI and should be taken into consideration in connection with the preoperative counselling, as urgency before the operation is predictive of patient satisfaction.¹⁷

Three years after TTV, the present patient population had a 60% improvement in their urgency symptoms, whereas 4.8% of the patients presented de novo urgency symptoms. After a mean of 10.5 years, de novo urgency was reported by six (6.6%) patients. Previously, de novo urgency or UUI has been reported in 1.5–22% patients after TTV during a follow up from 12 to 36 months.^{13,18} De novo urgency is regarded as the most common long-term adverse event after surgical treatment of female SUI. Indeed, it might be even more troublesome for the patient than preoperative SUI.¹⁹ In contrast, after the TTV, urgency symptoms will abate in 54–93% of patients.^{5,13} Increasing urgency rates during the follow up might preferentially relate to aging, as the incidence and severity of symptoms of overactive bladder increase progressively with age.^{20,21}

The TTV procedure is effective for the treatment of recurrent SUI when the follow-up time has been 20–60 months.^{22–24} Rezapour and Ulmsten reported an 82% cure rate and 8% significant improvement of stress urinary incontinence in the study population where some patients have had several operations before the TTV.²⁵ As repeat surgical intervention, medium cure rates after TOT seem to be lower than after TTV in women with ISD.^{22,26} The low pressure urethra and impaired urethral mobility are the risk factors predictive of failure of repeat incontinence surgery.^{22,27} Urodynamic examination is required to identify patients with ISD and to guide the surgeon to choose the TTV procedure in these cases. Previous operations might impair urethral function and increase the risk of complications as a result of scarring and altered anatomy. Thus, it is not surprising that the incidence of urgency and UUI are more common after recurrent operations than after the first operation. In the present study, patients operated on with TTV as a repeat procedure had the same long-term outcome than patients with primary SUI.

In the present study, three patients suffered from late tape-related adverse events at 1–11 years postoperatively. In all these cases, the initial TTV procedure and immediate recovery after that proceeded as expected. Two patients with retention and pain had the tape cut without any further problems. One patient had recurrent urinary tract infections and dysuria as a result of tape erosion into the bladder and had to undergo at least three cystoscopies to remove the visible tape from the bladder wall. Irritating symptoms, recurrent urinary tract infections and pain during urination might emerge several years after the primary operation, and need to be taken into consideration as a sign of late complication of TTV. Tape erosion might develop because of possible submucosal placement of the tape or pressure necrosis

of the bladder wall.^{28,29} In patients with prolonged or later-appearing urinary symptoms, a cystoscopy should be carried out, even many years afterwards.

The results of the present long-term follow-up study of patients with primary or recurrent SUI and concomitant procedures undergoing TTVT operation are encouraging. The TTVT shows excellent durable subjective and objective cure rates in SUI patients, and shows similar durable objective efficacy for SUI component of MUI patients. However, a long-term subjective cure might not be achieved by this procedure in MUI patients, even when they predominantly complain of SUI. The long-term complications of the TTVT are very few.

Acknowledgments

Statistician Mikko Taalikka assisted substantially with statistical analyses. Dr Robert Paul reviewed the language of this manuscript. The corresponding author has received grants from Turku University.

Conflict of interest

None declared.

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Appendix 1. Urinary Incontinence Severity Score (UISS)

		Not at all	Sometimes	Often
1. Do you experience urine leakage not related to effort or position (for example lying down)?				
2. Do you experience urine leakage to minor physical activity (e.g. walking or rising)?	Not at all	Sometimes	Often	
3. Do you experience urine leakage related to sudden, strong physical activity or even coughing or sneezing?	Not at all	Sometimes	Often	
4. Has urine leakage disturbed your daily chores (shopping, cooking, housecleaning etc.)?	Not at all	Sometimes	Often	
5. Has urine leakage disturbed your employment (client service, work performance etc.)?	Not at all	Sometimes	Often	
6. Are you afraid that others will notice your problem (fear of your odour or wetness etc.)?	Not at all	Sometimes	Often	
7. Do you have to restrict or give up social activities (such as visiting friends, physical activity, theatre, church etc.)?	Not at all	Sometimes	Often	
8. Do your incontinence symptoms disturb your sex life?	Not at all	Sometimes	Often	
9. Does incontinence cause irritation of your external genital organs?	Not at all	Sometimes	Often	
10. How often must you use a protectiveappy or pad?	Not at all	Sometimes	Often	

Appendix 2. Detrusor Instability Score (DIS)

Please circle the most suitable response to the questions below.

	0	1	2
1. How many times per day do you urinate?	5–7	8–10	Over 10
2. How many times at night do you have to get up to urinate?	0–1	2–3	Over 3
3. Do you feel there is still urine in the bladder after urinating?	No	Sometimes	Often
4. Does hurry and tension cause urge to urinate?	No	Slightly	Strongly
5. Do you have urinary leakage during stress (coughing, sneezing, laughing)?	Yes		On other occasions as well
6. Does the leakage of urine happen immediately in connection with stress?	Immediately		After some time
7. Do you feel need to urinate before the leakage of urine?	No	Slightly	Strongly
8. Have you had treated urinary infections during the past two years?	No	1–2	More than 2/chronically
9. How much is the amount of urinary leakage at a time?	Drops	A certain amount	Bladder empties completely
10. Can you stop the stream of urine while urinating?	Yes	Fairly well	No